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# NOTICE OF ALLOWANCE AND FEE(S) DUE

466 7590 08/20/2010

YOUNG & THOMPSON 209 Madison Street Suite 500 Alexandria, VA 22314

10/588.493

EXAMINER SNYDER, STUART

PAPER NUMBER

8341

ARTHNIT 1648 DATE MAILED: 08/20/2010

4001-1224

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. Maximilian Fleischer

TITLE OF INVENTION: BIOSENSOR AND METHOD FOR OPERATING THE LATTER

09/28/2006

APPLN, TYPE SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional NO \$1510 \$300 \$1810 11/22/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

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If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

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II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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appropriate. All further indicated unless corrects maintenance fee notifica	correspondence includir ed below or directed oth	ng the Patent, advance on herwise in Block 1, by (a	rders and notification of r a) specifying a new corres	pondence address; a	Il be mailed to the und/or (b) indicating	urrent c	orrespondence address as nte "FEE ADDRESS" for
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10/588,493	09/28/2006	Maximilian Fleischer	4001-1224	8341
466 7.	590 08/20/2010		EXAM	IINER
YOUNG & THO	MPSON	SNYDER, STUART		
209 Madison Stree	t	ART UNIT	PAPER NUMBER	
Suite 500 Alexandria, VA 22	2314	1648 DATE MAII ED: 08/20/201	0	

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 387 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 387 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

# Application No. Applicant(s) 10/588 493 FLEISCHER ET AL. Notice of Allowability Examiner Art Unit STUART W SNYDER 1648 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to 6/16/2010. The allowed claim(s) is/are 1,2,4-8 10-16 18 19. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). b) ☐ Some\* c) ☐ None of the: a) 🔯 All 1. A Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). \* Certified copies not received: \_\_\_\_\_. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. | Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date Information Disclosure Statements (PTO/SB/08). 7. X Examiner's Amendment/Comment Paper No./Mail Date

of Biological Material

4. ☐ Examiner's Comment Regarding Requirement for Deposit

8. T Examiner's Statement of Reasons for Allowance

Other .

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#### EXAMINER'S AMENDMENT/COMMENT

An examiner's amendment to the record appears below. Should the changes
and/or additions be unacceptable to applicant, an amendment may be filed as
provided by 37 CFR 1.312. To ensure consideration of such an amendment, it
MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in telephone interviews with Robert A. Madsen on 7/15/2010 and 8/3/2010.

The Specification is amended to add a section header saying "Brief Description of the Drawings" on page 3, line 29 immediately preceding the sentence that begins "Exemplary examples...".

The Claims are amended as follows:

- A biosensor for detection of an antigen (6) by means of an antigen/antibody coupling, consisting of the following elements:
- a silicon substrate (2),
- at least one interdigital electrode pair structure (12) of electrodes (13) arranged in pairs accommodated on the silicon substrate (2) with a spacing between the electrode pairs of maximum 1.0 μm,
- counter-electrode (11) accommodated on the silicon substrate (2),
- a reference electrode integrated onto the silicon substrate (2),
- a first layer made of protein (4) at least covering over the interdigital electrode structure (12),

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 a selective second protein layer applied over the first layer which contains a selected capture antibody (5) corresponding to the detecting antigen (6) and which can couple to the antigen, and

- -the capture antibody (5) is immobilized over the interdigital electrode structure (12) by the protein (4) of the first layer;
- wherein if an antigen (6) is bound to the capture antibody (5) and the enzyme-labeled detection antibody is (7) also bound to the antigen, an enzymatic release of a redox-reactive molecule on the sensor surface (1) occurs and a sensor signal being able to be read out at the interdigital electrode structure (12) is generated.
- The biosensor as claimed in claim 1, in which a signal is detected using alternating current or cyclic voltammetry.
- Cancelled.
- 14. A method for operation of the biosensor of claim 1 for detection of an antigen (6) by means of antigen/antibody coupling, comprising the following steps:
  - coating a biosensor constructed on a silicon chip with a protein base coating with a protein A, G or G' with simultaneous covering of interdigital electrode pair structures (12) on the surface of the silicon chip;

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 fabricating a further layer on the protein coating which contains a capture antibody (5) which is selected so that it can coupled with the antigen (6) sought;

- contacting the sensor surface (1) with a fluid to be analyzed;
- contacting the sensor surface (1) with an enzyme-labeled detection antibody (7);
- contacting the sensor surface (1) with redox-reactive molecule specific to the enzyme that labels the detection antibody (7); and
- monitoring a presence of a reaction product of the redox-reactive molecule on the sensor surface (1);
- wherein detection of the presence of the reaction product indicates the presence of the antigen.
- 16.The biosensor as claimed in claim 2, in which a signal is detected using alternating current or cyclic voltammetry.
- 17. Cancelled.
- 20. Cancelled.

## Continued Examination Under 37 CFR 1.114

 A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous

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Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/16/2010 has been entered.

# Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejection of claims 1-20 under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter, et al., El Shami, et al., Niwa, et al., and Pettit is moot in the case of claims 3 and 9 because of cancellation of the claims and withdrawn in the case of claims 1-2, 4-8, and 10-20 in view of Applicants' arguments and amendments filed 6/16/2010 and the Examiner's Amendment herein.

#### Conclusion

- Claims 1-2, 4-8 and 10-20 are allowed.
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on (571)272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/ Primary Examiner, Art Unit 1648 Stuart W Snyder Examiner Art Unit 1648

SWS